

PCT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: ✓

Davies Collison Cave
1 Little Collins Street
MELBOURNE VIC 3000

TUESDAY 10 FEB 1998
Replied 9.4.98

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing day/month/year	09 FEB 1998
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Applicant's or agent's file reference <u>1907226/EJH/MRO</u>	REPLY DUE within TWO MONTHS from the above date of mailing
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International application No. PCT/AU 97/00304	International filing date 16 May 1997	Priority Date 17 May 1996
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International Patent Classification (IPC) or both national classification and IPC

Int. Cl.⁶ G01N 33/68, 33/551; C12N 1/00

Applicant

(1) Women's & Children's Hospital
(2) MEIKLE, Peter J. et al.

1. This written opinion is the **first** (first, etc) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:

- | | | |
|------|-------------------------------------|--|
| I | <input checked="" type="checkbox"/> | Basis of the opinion |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input checked="" type="checkbox"/> | Certain observations on the international application |

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **17 September 1998**

Name and mailing address of the IPEA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer ISOBEL TYSON Telephone No. (02) 6283 2563
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I , Basis of the opinion

1. This opinion has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

☒ the international application as originally filed.

☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , filed with the letter of .

☐ the claims, Nos. , as originally filed,
Nos. , as amended under Article 19,
Nos. , filed with the demand,
Nos. , filed with the letter of .

☐ the drawings, sheets/fig , as originally filed,
sheets/fig , filed with the demand,
sheets/fig , filed with the letter of .

2. The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig

3. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 2,5,6,8-11,13-16,19,23-52	YES
	Claims 1,3,4,7,12,17,18,20-22	NO
Inventive step (IS)	Claims 2,5,6,8-11,13-16,19,23-52	YES
	Claims 1,3,4,7,12,17,18,20-22	NO
Industrial applicability (IA)	Claims 1-52	YES
	Claims	NO

2. Citations and explanations

D1 = Neurology, (1983 Jan.) 33(1) 57-66
D2 = J. Pediatrics, (1984 Feb.) 104(2) 232-6
D3 = Clinical Genetics; (1986 May) 29(5) 417-24
D4 = Eur. J. Biochem, (1979 Nov. 1) 101(1) 245-50
D5 = J. Clin.Invest., (1986 Feb.) 77(2) 568-74
D6 = Eur. J. Biochem, (1982 Apr. 1) 123(2) 317-21
D7 = Biol. Chem. Hoppe-Seyler, (1988 Apr.) 369(4) 297-302
D8 = US 5501957
D9 = Cancer Letters, (1996 Mar. 29) 101(2) 179-84

Novelty (N) Inventive Step (IS) Claims 1,3,4,7,12,17,18,20-22

D1,D2,D3,D4 and D5 are all directed to methods of assaying for detection of increased urinary free sialic acid excretion, which is associated with Salla disease (an LSD). On page 4 of the present application, Salla disease is one LSD selected as a target of the purported invention. Claim 1 is to a method of detecting an LSD by assaying for a marker associated with the LSD - sialic acid is considered to be one such marker.

In light of the above comments claims 1,3,4,7,12,17,18,20-22 are considered to be neither novel nor inventive.

D6 - D9 neither disclose nor teach toward the invention of the present application.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

On page 4, references to MPS1111A & MPS 1111C appear to be incorrect. In Table 1 on page 26 there are represented MPS 111A & MPS 111C, which would appear to be correct.

PATENT COOPERATION TREATY

**International Application No
PCT/AU97/00304**

**Applicant:
WOMEN'S AND CHILDREN'S HOSPITAL**

11 March 1998

SCHEDULE of proposed amendments desired to be made to the abovementioned specification in response to the Written Opinion mailed on 23 January 1998.

- 1. Cancel claims pages 47-52 (claims 1-52 inclusive) and substitute with new claims pages 47-53 (claims 1-51) as attached hereto.**

MADDERNS

CATHERINE M HUSTWICK

**To: THE COMMISSIONER OF PATENTS
WODEN ACT 2606**